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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/613,468 07/10/00 WEIDNER

M 04590461P

002292 HM12/0927
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EXAMINER

GOLLAMUDI, S

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

09/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/613,468	Applicant(s) WEIDNER, MORTEN SLOTH	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

- I. Claims 1-9 drawn to the instant composition, classified in class 424, subclass 439.
- II. Claims 10-16 and 23-25, drawn to the method of preparing the instant composition, classified in class 424, subclass 439.
- III. Claims 17-18, drawn to the method of treating hypersensitivity or inflammation, classified in class 424, subclass 439.
- IV. Claim 19, drawn to the method of treating autoimmune disorders or chronic inflammatory, classified in class 424, subclass 439.
- V. Claim 20, drawn to the method of treating psoriasis, etc., classified in class 424, subclass 439.
- VI. Claim 21, drawn to the method of treating pain, classified in class 424, subclass 439.
- VII. Claim 22, drawn to the method of treating prostatitis, classified in class 424, subclass 439.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process

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(MPEP § 806.05(f)). In the instant case, the instant composition may be prepared in distinct and different steps. The instant composition may be prepared differently according to the disease as seen in the instant claims.

Inventions I and III, I and IV, I and V, I and VI, and I and VII respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

For instance, invention I, the instant composition, can be used in a variety of methods to treatment. Invention I may be used in invention III, the method of treatment of hypersensitivity or it can be used in invention IV, the instant composition usage for distinct diseases. Thus, the composition of invention can be used in a materially different process of using the composition.

Invention I and invention IV are distinct in that invention I one may be used for the process of use of invention IV or for instance in the process of use of invention III, two materially different processes of using invention I.

Invention I and invention V are distinct in that the invention I one may be used for the process of use of invention V or for instance in the process of use of invention IV, two materially different processes of using invention I.

Invention I and invention VI are distinct in that the invention I one may be used for the process of use of invention VI or for instance in the process of use of invention V, two materially different processes of using invention I.

Invention I and invention VII are distinct in that invention I one may be used for the process of use of invention VII or for instance in the process of use of invention VI, two materially different processes of using invention I.

Inventions II and III, II and IV, II and V, and II and VI, and II and VII respectively are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different in functions.

Invention II and invention III are distinct in that invention II may be prepared for invention III or for instance it may be prepared for invention IV. Thus, the inventions have different functions and effects.

Invention II and invention IV are distinct in that invention II may be prepared for invention IV or for instance it may be prepared for invention III. Thus, the inventions have different functions and effects.

Invention II and invention V are distinct in that invention II may be prepared for invention V or for instance it may be prepared for invention IV. Thus, the inventions have different functions and effects.

Invention II and invention VI are distinct in that invention II may be prepared for invention VI or for instance it may be prepared for invention V. Thus, the inventions have different functions and effects.

Invention II and invention VII are distinct in that invention II may be prepared for invention VII or for instance it may be prepared for invention VI. Thus, the inventions have different functions and effects.

Inventions III and IV, III and V, III and VI, and III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions.

Invention III and invention IV are distinct in that the inventions are different and distinct methods of treating distinct diseases.

Invention III and invention V are distinct in that the inventions are different and distinct methods of treating distinct diseases.

Invention III and invention VI are distinct in that the inventions are different and distinct methods of treating distinct diseases.

Invention III and invention VII are distinct in that the inventions are different and distinct methods of treating distinct diseases.

If group I or group II is elected, then the applicant may choose a method of treatment.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

If group I is elected then the following election of species is required between the instant compositions formulation as a fluid, ointment, gel, liniment, and emulsion and the instant composition formulation as an aerosol. An aerosol requires a propellant and pressurized formulation.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

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the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

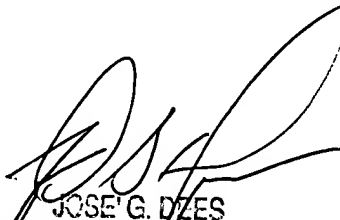
A telephone call was made to Mr. Svensson on August 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

SSG


JOSE G. DEES
SUPERVISORY PATENT EXAMINER
1616